

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021						Introduction 1	Гуре:	New Item		X	Final Version			Date:	12/28	/2022	
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/AN	DA/BLA (drug); PMA/510	(k)(med devic	e):	215	5420						ture Range	Controlled Room		and 25 C (68	° – 77° F)		
Medical Device Class, if applicat																	
DUNS:	82-677-4775										mperature Range F	Requirement					
Proprietary Name (If Applicable) a	Ind Established Name:	Saprop	oterin Dihydrochloride Powd		on 100mg 30ct	UPC:					te in)						
Selling Unit NDC:	31722-047-30		Unit of Use NDC: CVX Code:			MVX Code:	3317220	47302		Notes							
02.						MITA OOUC.											
Description:	Sapropterin Dihydrochlor	ide Powder to	r Oral Solution 100mg -								oduct to be shipped				No No		
Active Ingredient(s): Sapropterin Dihydrochloride No																	
b. Contact for temperature excursion questions:																	
	JRL for Additional Product Information: www.camberpharma.com						Name: So										
Address:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2: NJ Zip: 08854			Number:				732-529-042					
City: Key Contact:	Piscataway Customer Service				State: Email:								somaraju@heterousa.com				
Phone Number:	1-866-827-3647				customerservice@camberpharma.com 732-562-8788			c. Special red	ulations f	or product in any	states?			No			
Product Therapeutic Classification		/lalanine Hydr	oxylase Activator							-	eturns requirement				No		
	ADDITIONAL		FORMATION			PRODUCT	DESCRIPT	ION INFORMATION	d. Store prod	uct (unit c	of sale) upright?				No		
The product is?			Is the Product	Direct-Ship O	nly				1	Protect p	product (unit of sa	le) from light?			No		
a legend device?	No		Is the Product	Unit Dose		Size:	30	lot	e. Shelf life:							Months	
if yes, enter class #			Orphan Drug Status			0120.		_	1	Initial sh	elf life at launch (i	if different):				Months	
a product kit?	No		FDA Approval Status			Strength:	10	00mg				ORDER INFORM					
if yes, list NDCs of component parts			FDA Approval Status				P	owder for Oral Solution					IATION				
reverse numbered?	No					Dosage Form	m: (``			Unit of S	ale		What is the	NDC selling	unit?		
co-licensed?	No		Allergens Present							-	Bottle		1 carton of 3				
latex-free?	Yes					Product Sha	N/	A		x	Box/Carton		(Write-in, e.g	g. 1 Box of 10) Vials)		
preservative-free?	No					eutor enta					Ampule						
correctional institution block? opioid?	No					Product Cole	or: Of	f-White to Yellow Powde			Glass Tube		Minimum or	der quantity	?	Yes	
Cannabinoid?	No No		Country of Origin	India			N/	Δ			Vial Liquid Sgl						
If Unit Dose, is item bar coded to u			obuility of origin	India		Product Imp	rint:	~			Vial Liquid Multi		If Yes, how I	many of whi	ch package t	vpe?	
hospital scanning?	Yes		Is this product covered u	under the							Vial Powder Sql			Each			
If Unit Dose, indicate NDC here:	31722	2-047-01	Trade Agreements Act (TAA)?	No						Vial Power Multi		1	Inner/Carton	Pack		
										Other: Write In			Case				
			FOR GENERIC DRUG PR	ODUCTS													
Authorized Generic *If Authorized Generic, other								PHARMACY ORDER / BILL UNIT									
L Orenne Back Beting:	AB					anonzeu Generie		elds are not applicable	Rec. sell unit	to custon							
I. Orange Book Rating: AB Section relids are not app II. Generic Equivalent to What Brand?: Kuvan® for Oral Solution							Rec. sell unit to customer? Rx billing unit to pharmacy:										
							(Write-in, e.g. 1 Vial) Gram										
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Milliliter																	
											1754						
Does supplier meet DSCSA definit Is product exempt from DSCSA?	tion of manufacturer?		Yes	_	GLN:	0331722000000					IIEW	I AND PACKING I	NFORMATION				
					GCP:				1			Dimonsi	ons (US msm	te)	Volume	Saleable #	
If yes, select exemption: Other exemption - Write in:					GUP:				1		Weight Lbs.	Dimensi	Width	Height	Volume (Cube)	Saleable # Pieces	
Is product repackaged?			No		If yes, was or	iginal product pur	chased		Item/Each:		0.45				(0000)		
Is product sold by manufacturer's	exclusive distributor?		Yes		direct from m						0.15	4.5	2.5	2.875		1	
Has FDA granted waiver/exception			No		Provide sour	ce manufacturer fo	or repacka	ged product	Box/Carton/B	Bundle/							
If yes, attach documentation from	m FDA.								Inner Pack:								
		GTI	N AND HIBCC PRODUCT I	NEORMATION					Case:		4.1	14.31	11.06	6.5		24	
									Pallet:								
Saleable Unit of Measure	Saleable	Quantity	HIBCC		GTI	N-14	ι	Unit of Use GTIN-14									
X Item/Each							00331722047302										
Box/Carton/Bundle/Inner Pack						17000 17000				COST INFORMATION			WHOLESALER USE ONLY:				
X Case Pallet	2	24			203	31722047306	-		Regular Cost				Vendor #:				
Faller									Invoice Cost			\$810.00	Whsl. Code	#:			
										,		\$010.00	Fineline Coo				
									As of date:				1				
									1								
μ									1				ļ				
+Blass and the state of the			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza				RODUCT PACK								
*Please provide any additional info	ormation on page 2.					See new p. 3 for	Designate	ed Drop Ship Only.		Signatur	e:						

HDA Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 For Des	signated Drop Ship Only Products, Please Use Page 3						
MATERIA	L HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? N b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? N Is the product a CA Prop 65 reproductive toxicant? N Does the product label bear a CA Prop 65 warning? C. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? N	o x Organic Corrosive o Inorganic Oxidizer o Steroid/Androgen Contact Hazard o Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Storage Level:						
e. Does the product contain DET if it is product regulated for shipment by DOT? Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class							
d. Packing Group							
e. Inhalation Hazard?	o EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)							
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:						
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	o Med Guide Required No Limited Distribution Requirement Image: Comments / Details: (For example, iPledge program?) Image: Comment of the second secon						
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Parister No.						
SP#ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments						
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? ARCOS Reportable? Schedule No. No CLASS OF TRADE RESTRICTION: No No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 1-866-827-3647						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	contact - customerservice@camberpharma.com						
No resultation: seed Yes if sold or fetal pharmacy, nospitals, cuinces and physician offices If the second seed Yes if sold or fetal pharmacy, nospitals, cuinces and physician offices Restricted to retail pharmacy only: N Restricted to hospital, clinics, and physician offices only: N Restricted from US territories? (explain in comments) N Comments: Image: Comments in the second s	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
MISCEL	ANEOUS NOTES and/or Image of Product Barcode:						



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Version 2021 FOR DESIGNATED DROP SHIP PRODUCT ONLY - if	not a designated drop ship, do not complete.
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?